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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,213	10/20/1999	TIMOTHY J. O'BRIEN	D6064CIP	3804

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EXAMINER

HARRIS, ALANA M

ART UNIT PAPER NUMBER

1642

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/421,213

Applicant(s)

O'BRIEN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 25-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 22-24 is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Arguments***

1. Claims 1-52 are pending.

Claims 1-21 and 25-52, drawn to non-elected inventions are withdrawn from examination.

Claims 22 and 24 have been amended.

Claims 22-24 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Priority***

3. Applicants are afforded domestic priority under 35 U.S.C. 120 based upon the U.S. serial application 09/027,337, now U.S. patent 5,972,616, filed February 20, 1998.

***Drawings***

4. The drawings were objected to because of reasons cited on form PTO 948 completed by draftsman. Applicants are advised to review MPEP 608.01(f), 37CFR 1.84, with particularity section (iv).

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 22 and 24 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of Applicants' amendments to the claims.

***Claim Rejections - 35 USC § 102***

6. The rejection of claim 24 under 35 U.S.C. 102(a) as being anticipated by Lin et al. (The Journal of Biological Chemistry 274(26): 18231-18236, June 25, 1999) is withdrawn in light of Applicants' newly established priority date of February 20, 1998.

***Claim Rejections - 35 USC § 103***

7. The rejection of claims 22-24 under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (The Journal of Biological Chemistry 274(26): 18231-18236, June 25, 1999) is withdrawn in light of Applicants' newly established priority date.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 103***

8. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession #W22987 (October 8, 1997), in view of Lerner (Nature 299:592-596, 1982).

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Applicants argue in anticipation of the instant rejection that "...claims of the instant application are drawn to an antibody specific for TADG-15 protein" and that "[a]ntibodies raised against the polypeptide of Accession #W22987 are not specific for TADG-15 protein". Applicants admit the said antibodies would bind to both the polypeptide of Accession #W22987 and TADG-15 resulting from cross-reactivity rather than specificity. Applicants further assert the term "specific" is the same as "exclusive" and such is readily understood by one of ordinary skill in the art. These arguments have been fully considered and found unpersuasive.

Applicants are directed to Roitt et al. (Immunology, third edition., Mosby, St. Louis, pages 6.4 and 6.5, 1993). Roitt teaches in the last sentence of the bridging paragraph of pages 6.4 and 6.5 that "when some of the determinants of an antigen, [for instance] A, are shared by another antigen, B, then a proportion of the antibodies directed to A will also react with B. This phenomenon is termed cross-reactivity." See Fig 6.8 on page 6.4. Furthermore, specificity is not equivocal to exclusivity. Roitt continues to state on page 6.5, column 2, second paragraph, "The specificity of a population of antibodies is not due to each antibody reacting exclusively with the induction antigen."

Accordingly, as set forth in Paper number 10, page 5, paragraph 11 Accession # W22987 teaches a polypeptide sequence comprising a fragment of the amino acid sequence of the TADG-15 protein. Accession # W22987 does not teach purified antibodies which specifically bind the specified polypeptides, a means to detect said antibody, nor a kit.

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However, Lerner teaches that antibodies can be generated against peptides of at least 15 amino acids, representative of virtually any part of the surface of a protein can elicit antibodies reactive with the native molecule. It would have been *prima facie* to one of ordinary skill in the art at the time the claimed invention was made to select specific regions of the polypeptide of Accession # W22987 or the entire fragment in order to produce antibodies reactive with said TADG-15 protein, as taught in Lerner. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Lerner, that such antibodies are powerful aids in the study of the polypeptide.

In addition, although the claims recite a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the reference read on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and methods of detection, diagnostics and therapies also were well known and available to the ordinarily skilled artisan. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

### **Conclusion**

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.  
October 29, 2002

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Attachment for PTO-948 (Rev. 03/01, or earlier)  
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.